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(56) Documents Cited
GB 2281863 A EP 0275642 A1 US 4448198 A
US 4346715 A US 4016886 A

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(54) Abstract Title
Surgical diathermy apparatus

(57) Apparatus for destroying tumours and infections includes at least three cylindrical or needle electrodes 8 connected to designated terminals of a polyphase high frequency generator 1 by conductive tracks 3 on a printed circuit board 2 which acts as a template for positioning the electrodes 8 relative to tissue 13 to be treated. The electrodes 8 can be moved axially through guide tubes 5,6 soldered at desired angles to the tracks 3. Alternatively, the guide tubes may be clamped using spherical portions of the tubes. The template may be a set of adjustable guide blocks, or an insulating sheet, and the electrodes may be connected to the generator by flexible leads. A rigid flange (not shown) may contact the tissue 13 to form a chamber from which air is evacuated, pulling heated tissue away from adjacent tissue. The flange may be cooled by air flow.

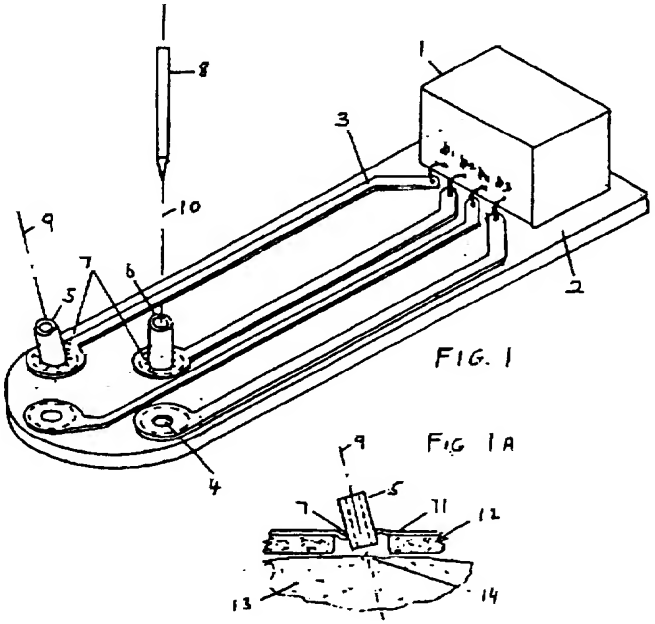

FIG. 1

FIG 1A

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IMPROVEMENTS IN RELATION TO APPARATUS FOR SURGICAL DIATHERMY

The present invention relates to improvements in relation to apparatus for surgical diathermy.

In the prior art, such as British Patent Application no. 2281863, apparatus exists for causing high frequency electric currents to pass through living tissue in order to generate heat. This may be for the purpose of cutting or destroying the tissue, or for causing a local temperature rise the effect of which will be to degrade infections or tumour cells. This effect may be produced either alone or in combination with drugs, chemical reagents, or other sources of energy such as ionising radiation.

In one particular class of application, known as interstitial diathermy, electrodes are inserted into living tissue with a view to creating a local temperature rise within a defined volume of the tissue. There are however difficulties in creating a uniform temperature rise throughout the volume of the tissue using two electrodes. This is because of the need for electrodes to be small in size to minimise mechanical damage to the tissue, even though small electrodes cause local concentrations of current flow.

This has led to the concept of a set of three or more electrodes inserted into the surface of living tissue around the periphery of the volume of tissue to be heated, whereby each of the electrodes tends to be placed on the surface of the living tissue where its corresponding supply phase would appear on a vector diagram. The electrodes are wired to the polyphase outputs of a high frequency electrical generator operating at a frequency greater then 200 kHz. The polyphase outputs may be provided by transformers having isolated secondary windings, which will cause

current flow from any one of the electrodes only to other electrodes of the set, but not to equipment earth.

Distances on a vector diagram being proportional to voltage differences, voltages appear between pairs of electrodes in proportion to their physical spacing, and accordingly heating effects will be distributed widely through the volume of tissue, provided that there exists an assured wiring connection between each electrode and an appropriate supply phase.

In order to establish such a correspondence between a polyphase output of the high frequency electrical generator and the relative position of an individual electrode of the set, the electrodes may be mechanically fixed to a common insulated plate or holder prior to insertion into the living tissue.

Such fixing of electrodes does not however allow for the situation encountered in practice where electrodes need to be inserted at uneven spacings or when their respective longitudinal axes are not parallel. This situation may be encountered owing to the non-uniformity of living tissues, the presence of blood vessels and membrane boundaries, or the need to keep electrodes clear of critical biological structures.

If however the electrodes are not inserted in an accurately reproducible way, it may be difficult to implement a previously computed treatment plan or to verify the likely effects of the treatment prior to operation.

In other instances, it may be desirable to adjust the positioning of electrodes after insertion, in order to create a clamping action.

According to a first aspect of the present invention, there is provided an apparatus for diathermy, comprising:

a set of at least three cylindrical or needle-shaped electrodes adapted to be (a) connected to respective output terminals of a polyphase electrical generator arranged to operate at a frequency in excess of 200 kHz, and (b) inserted through the surface of living tissue to a required depth,

positioning means attachable to a required location on the surface of the living tissue and defining the points of entry of the electrodes into the tissue, and

connection means for electrically connecting each of the electrodes to a designated one of the output terminals corresponding to the position of its point of entry with respect to others of said electrodes,

whereby said electrodes are movable for purposes of insertion along axes which may be determined by the user and need not be mutually parallel.

Accordingly, this aspect of the invention allows electrodes to be individually inserted into living tissue during the course of a surgical operation or other medical treatment, in a desired or measurable geometrical relationship, also preserving the required connection sequence between said electrodes and a polyphase electrical generator.

Preferably, the positioning means comprises a planar template.

The planar template may be of a material which includes a dye which, in use, changes colour according to the temperature of the surface of the living tissue.

The apparatus may comprise guidance means attached to or comprised within said template, whereby the electrodes of said set are guided to slide axially therein, the guidance means being adjustable by the user in their spacing and/or their angular orientation with respect to said tissue. The guidance means may comprise guide tubes, each fitted to a guide aperture

on the template, said guide tubes being mechanically linked by said template.

In a first preferred embodiment, said connection means comprise printed circuit tracks, preferably made of soft electrically conductive material such as copper, applied to a sheet of insulating material which constitutes said template. To said tracks is mounted a polyphase converter having isolated secondary windings as exemplified in my British patent application no. GB 2299216. Guide tubes are formed by short lengths of metal tubing each passing through a guide aperture in one of said tracks and affixed thereto, preferably by formation of a solder bridge, the necessary clearance hole in said insulating material being oversized to permit flexure of said printed circuit track in the vicinity of said guide tube. Such flexure can be used to adjust the orientation of said guide tube when affixed to said template.

In another embodiment, designed to allow of adjustment both before and during use, a said guide tube carries a spherically machined portion of its periphery which fits to a guide hole of lesser diameter in said template or printed circuit track, said guide hole being tapered to allow variation in the angular alignment of said guide tube and with clamping means for clamping said spherically machined portion into said guide hole after the orientation of its axis has been set. Said clamping means may be a disc of insulating material drilled in conformity with said template and forced towards it by a screw fastener.

Connection means may comprise flexible wires, attached to the output terminals of said polyphase electrical generator, each of said wires attached to one of said electrodes preferably via a sleeved socket connector. Each of said wires is preferably coded

uniquely, for example by the colour of its connector sleeve, so that its corresponding electrode may be fitted within only one of said guide apertures.

A template may comprise a sheet of insulating material, pierced with a ring of holes to constitute said guidance means, and manufactured from a type of insulating material into which is incorporated a temperature sensitive dye so that the visible colour at any point of the surface of said template is a measure of the temperature of the underlying tissue and also said template restricts the evaporation of moisture from said tissue which would otherwise cause an undesired loss of heat. Preferably, such a flexible template is provided with an adhesive layer to create close mechanical and thermal contact with said tissue.

Alternatively, the material of said template, though rigid in use, may be capable of distortion when treated with solvent or heated to an elevated temperature, said template retaining its modified shape while in use and thereby displacing the axes of one or more electrodes. Slots may be cut in the said template to render it more flexible.

In a further improvement, a guide tube or guide aperture has a unique internal cross-section which corresponds to the external dimensions of only one of said connectors, to create assured correspondence between guide apertures and generator outputs.

In a third embodiment, the equivalent of a template is created by extending the overall diameter of a guide tube or a connector sleeve to approximate the required spacing between electrodes, thus forming guide blocks which may be assembled and then tied or clamped or otherwise secured together into a continuous ring which renders a separate template unnecessary. Spacers may be interposed to increase the spacing between electrodes. Wires and electrodes remain

insulated.

It is known that effective hyperthermia treatment requires both the generation of heat as already described, and also its safe dispersal in order to minimise damage to nearby tissue which does not require and would be damaged by such treatment. Avoidance of unnecessary physical contact between treated and untreated tissues is therefore desirable, along with physical steps to extract heat from where it is not required.

The positioning means may have a downwardly-projecting flange extending from a lower surface thereof, the flange, in use, contacting the surface of the living tissue thereby to form a chamber defined by the surface of the living tissue, the flange and the lower surface of the positioning means.

According to a second aspect of the invention, there is provided apparatus for diathermy, comprising:

at least three electrodes adapted to be (a) electrically-connected to respective output terminals of a polyphase electrical generator, and (b) inserted through the surface of living tissue to a required depth; and

positioning means attachable to a required location on the surface of the living tissue and defining the points of entry of the electrodes into the tissue,

the positioning means having a downwardly-projecting flange extending from a lower surface thereof,

the flange, in use, contacting the surface of the living tissue thereby to form a chamber defined by the surface of the living tissue, the flange and the lower surface of the positioning means.

Preferably, the flange projects downwardly from the lower surface of the positioning means within the

area defined between the points of entry of the electrodes, and the lower surface of the positioning means has one or more downwardly projecting members at or near the periphery of the template.

The apparatus may further comprising evacuation means for creating a partial vacuum in the chamber. The evacuation means comprises a venturi tube, which may have an air supply which is also connected to cooling means arranged to direct air against the electrodes and/or said one or more downwardly-projecting members.

Thus, this invention further provides for a separation to be created between treated and untreated tissues by variations in atmospheric pressure.

The template may be made of a rigid material and provided with the suction annulus so that, when air pressure is reduced below atmosphere, the template is supported against said tissue near its periphery so that the portion of said tissue in which heat is to be generated will be pulled away from any neighbouring tissue to which it is not firmly attached, thereby restricting the transfer of heat to said neighbouring tissue.

The template may carry means to direct jets of air for cooling purposes as described in my British Patent Application No. 9801315.4, upon said electrodes, which are preferably made of material such as copper having a high thermal conductivity. Said electrodes may be provided with indicator elements each comprising an exposed surface to which is applied temperature sensitive paint or material of known infra-red emissivity. In a further improvement, the air before it enters said jets may pass through a venturi tube known in the prior art which serves to create a reduced pressure in a suction annulus as previously described.

For a better understanding of the invention, and

to show how the same may be carried into effect, reference will now be made, by way of example only, to the accompanying drawings, in which:-

Figure 1 is a perspective view of first diathermy apparatus in accordance with the present invention;

Figure 1a is a partial sectional view of a guide aperture of the apparatus of Figure 1;

Figure 2 is a partial sectional view of a second diathermy apparatus in accordance with the present invention;

Figure 3 is a perspective view of a third diathermy apparatus in accordance with the present invention;

Figure 4 is a perspective view of a fourth diathermy apparatus in accordance with the present invention; and

Figure 5 is a sectional view of a fifth diathermy apparatus in accordance with the present invention.

Referring to Figs 1 and 1a, a polyphase electrical generator 1 is mounted to a template 2 made from a sheet of insulating material having printed circuit tracks 3. Guide apertures 4 are pierced through the tracks 3. Guide tubes 5, 6 are fitted to guide apertures 4 and attached by a fillet 7 of solder or conductive cement. Electrodes 8 slide within and are electrically connected to said guide tubes 5, 6, and are thus capable of being individually inserted into the tissue to be heated.

Referring to Fig 1a, the longitudinal axes 9 and 10 of guide tubes 5 and 6 need not be mutually parallel, because that portion of the conductive track 11 from which the insulating laminate 12 has been cut away is capable of distortion. This is in addition to the flexibility afforded by the soldering or cementing process. Thus, an electrode inserted into guide tube 5 along axis 9 would enter tissue 13 at entry point 14.

Fig. 2 shows an arrangement similar to that of Fig. 1a, except that a guide tube 15 has a spherically machined portion 16 of its periphery which may be clamped into a hole of lesser diameter in template or printed circuit 17. The hole has sufficient clearance to allow angular movement of the guide tube 15 until such time as a clamping force is applied by screw 18 via clamping plate 19.

Fig. 3 shows the basic arrangement of a polyphase electrical generator 20 with output terminals 21 to which are attached flexible lead assemblies 22, 23. Each lead assembly 22, 23 carries a sleeved connector 24, 25, which is unique in colour or in its departure from a cylindrical shape. A template 26 carries pierced holes 27 to carry guide tubes 24, 25 or to perform the function of guide tubes 24, 25. Guide tubes 24, 25 need not be of a conductive material. In a further improvement (not shown), hole 27 may be shaped to allow insertion of one connector sleeve, but not of other connector sleeves, as a safeguard against operator error. The template 26 has slots 28, whereby the material of said template is weakened making it readily capable of distortion causing an attached electrode to depart from a standard position or angular relationship inherent in the template as manufactured.

The template 2, 17 or 26 preferably incorporates a temperature-sensitive dye, whereby the surface temperature pattern in the tissue to which the template is applied may be estimated by the operator as heating progresses and heat is subsequently distributed by thermal conduction.

Fig. 4 shows an alternative embodiment in which connector sleeves are shaped so as to constitute guide blocks 29-32, with guide apertures 33-36. Guide blocks 29-32 are also transversely drilled at their edges 37, whereby they may be conveniently retained together by a

wire ring 33 or other means. An optional spacer 39 is shown as having been used to increase the spacing between the electrodes held in guide blocks 29 and 30.

Fig. 5 shows an apparatus in which the template 2 carries an air duct formed by a tube 40, the wall of which is pierced adjacent to the positions of electrodes 41, 42. A supply of air at positive pressure to the tube 40 is thereby directed to cool electrodes 41, 42, heat being thereby drawn out of the tissue by the electrodes 41, 42.

The supply of air to the tube 40 passes through a venturi tube 43 which is connected to an elastomeric suction annulus 44. In use, this suction annulus 44 contacts the skin forming a chamber from which air is evacuated by the action of venturi tube 43. Thus, the tissue to be heated is pulled away from contact with other tissues. A rigid annular flange 45 extends around the outside of the template 2 and is pressed against the tissue by reaction of the suction force. Said flange may be of high thermal conductivity and also cooled by an air flow directed towards it by apertures in tube 40. In some embodiments, the flange 45 is replaced by a series of downwardly-projecting members spaced around the periphery of the template 2. Cooling members (not shown) in contact with the tissue may be included to enhance the cooling effect.

CLAIMS:

1. Apparatus for diathermy, comprising:

a set of at least three cylindrical or needle-shaped electrodes adapted to be (a) connected to respective output terminals of a polyphase electrical generator arranged to operate at a frequency in excess of 200 kHz, and (b) inserted through the surface of living tissue to a required depth,

positioning means attachable to a required location on the surface of the living tissue and defining the points of entry of the electrodes into the tissue, and

connection means for electrically connecting each of the electrodes to a designated one of the output terminals corresponding to the position of its point of entry with respect to others of said electrodes,

whereby said electrodes are movable for purposes of insertion along axes which may be determined by the user and need not be mutually parallel.

2. Apparatus according to claim 1, wherein the positioning means comprises a planar template.

3. Apparatus according to claim 2, wherein said planar template is of a material which includes a dye which, in use, changes colour according to the temperature of the surface of the living tissue.

4. Apparatus according to claim 2 or claim 3, comprising guidance means attached to or comprised within said template, whereby the electrodes of said set are guided to slide axially therein, the guidance means being adjustable by the user in their spacing and/or their angular orientation with respect to said tissue.

5. Apparatus according to claim 2 or claim 3, wherein said template is a printed circuit having conductive tracks applied to a sheet of insulating material, and said guidance means is a set of hollow

metal guide tubes soldered or otherwise affixed to said tracks through oversized holes which permit a degree of movement prior to fixing, or distortion of said tracks, whereby the orientation of said tubes may be individually adjusted by a user.

6. Apparatus according to claim 2 or claim 3, wherein said guidance means comprises a plurality of hollow tubes, the surface of at least one of which has a spherically-shaped portion which is arranged to be clamped by a clamping mechanism into a guide aperture of the template, the guide aperture having a diameter smaller than that of the spherically-shaped portion, whereby the angle of the longitudinal axis of the tube is movable relative to the plane of the template.

7. Apparatus according to any one of claims 2 to 6, wherein the template is slotted to render it flexible, and wherein the material of the template is capable of distortion when treated with a solvent or heated to an elevated temperature, retaining its modified shape thereafter while in use.

8. Apparatus according to any one of claims 2 to 7, wherein the connection means comprises flexible leads, each lead and corresponding location on said template being identified by a colour code.

9. Apparatus according to any preceding claim, wherein the electrodes are attached to said output terminals by flexible leads via individual connectors, each of said connectors being of a unique external cross section identifying with the internal cross section of only one of said positioning means,

10. Apparatus according to any preceding claim, wherein the positioning means comprises guide blocks through which said electrodes pass or are otherwise positioned, the guide blocks being shaped and/or colour coded and arranged so as to be clamped together or threaded to a common circumferential member in a

predetermined sequence, with optional spacer elements in order to bring said electrodes into a desired and reproducible geometrical relationship.

11. Apparatus according to any preceding claim, wherein the positioning means has a downwardly-projecting flange extending from a lower surface thereof, the flange, in use, contacting the surface of the living tissue thereby to form a chamber defined by the surface of the living tissue, the flange and the lower surface of the positioning means.

12. Apparatus for diathermy, comprising:

at least three electrodes adapted to be (a) electrically-connected to respective output terminals of a polyphase electrical generator, and (b) inserted through the surface of living tissue to a required depth; and

positioning means attachable to a required location on the surface of the living tissue and defining the points of entry of the electrodes into the tissue,

the positioning means having a downwardly-projecting flange extending from a lower surface thereof,

the flange, in use, contacting the surface of the living tissue thereby to form a chamber defined by the surface of the living tissue, the flange and the lower surface of the positioning means.

13. Apparatus according to claim 11 or claim 12, wherein the flange projects downwardly from the lower surface of the positioning means within the area defined between the points of entry of the electrodes, and the lower surface of the 0positioning means has one or more downwardly projecting members at or near the periphery of the template.

14. Apparatus according to claim 11, 12 or 13, further comprising evacuation means for creating a

partial vacuum in the chamber.

15. Apparatus according to claim 14, wherein the evacuation means comprises a venturi tube.

16. Apparatus according to claim 15, wherein the venturi tube has an air supply which is also connected to cooling means arranged to direct air against the electrodes and/or said one or more downwardly-projecting members.

17. Apparatus for diathermy substantially as hereinbefore described with reference to and/or as shown in any one of the accompanying drawings.

The Patent Office

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Application No: GB 9824895.8 **Examiner:** David Brunt
Claims searched: 1-17 **Date of search:** 22 February 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5R (RHCC, RHCE, RHEPX)

Int Cl (Ed.6): A61B (17/39), A61N (1/32, 1/40)

Other: Online: EDOC, JAPIO, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2281863 A	(WALTON)	-
A	EP 0275642 A1	(TAKASE)	-
A	US 4448198	(TURNER)	-
A	US 4346715	(GAMMELL)	-
A	US 4016886	(DOSS)	-

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

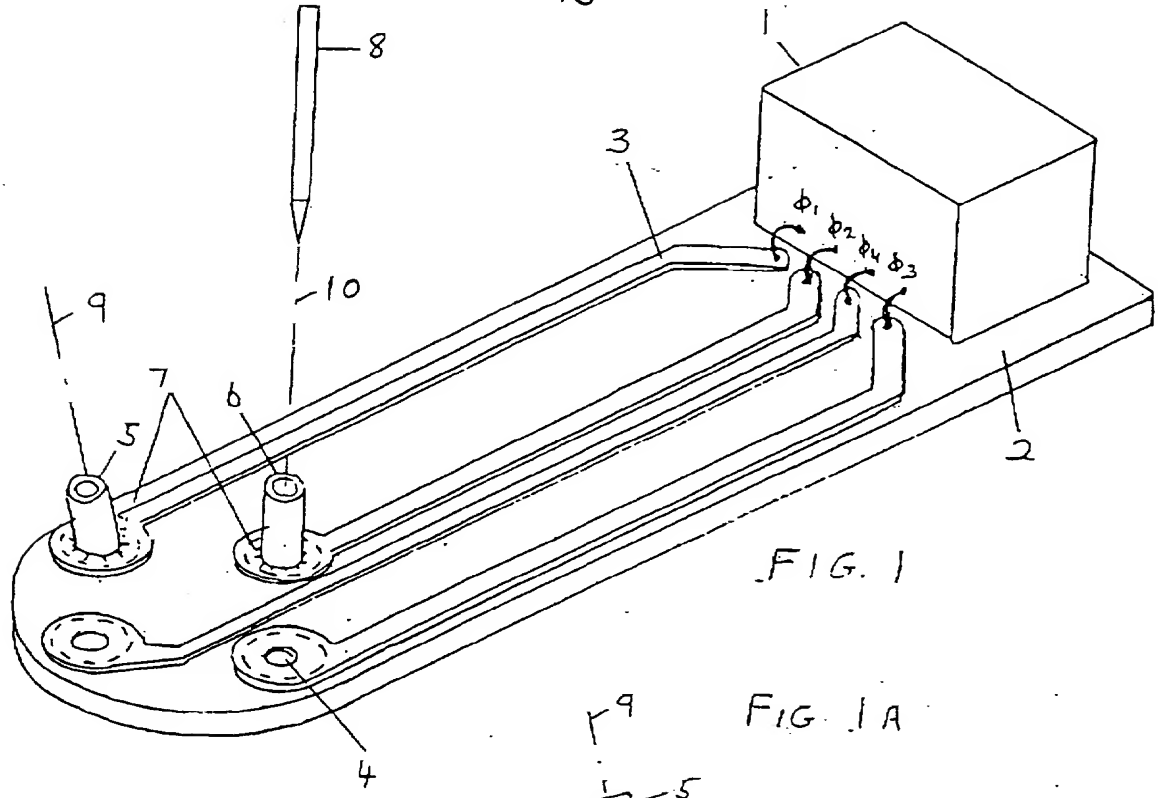

FIG. 1

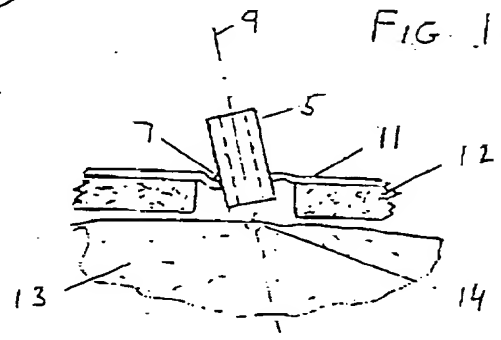

FIG. 1A

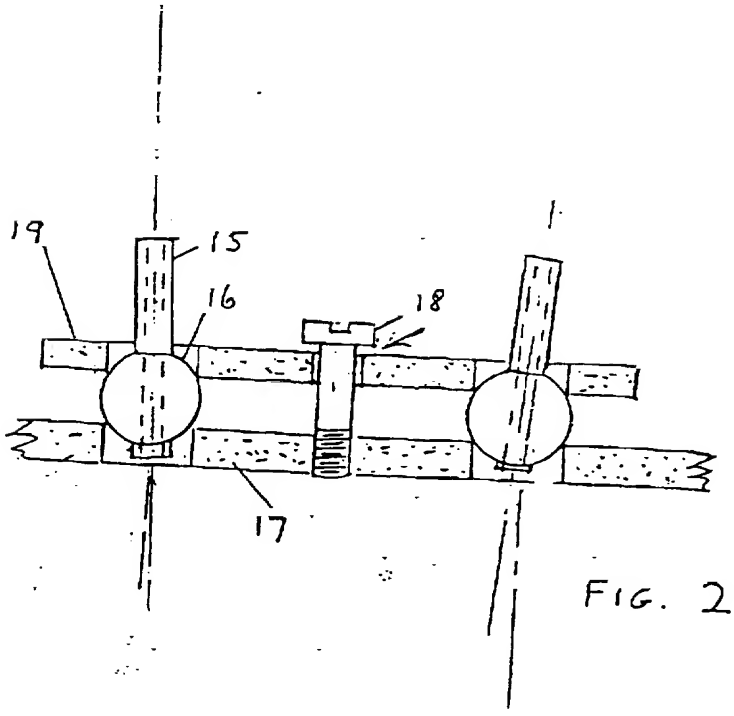

FIG. 2

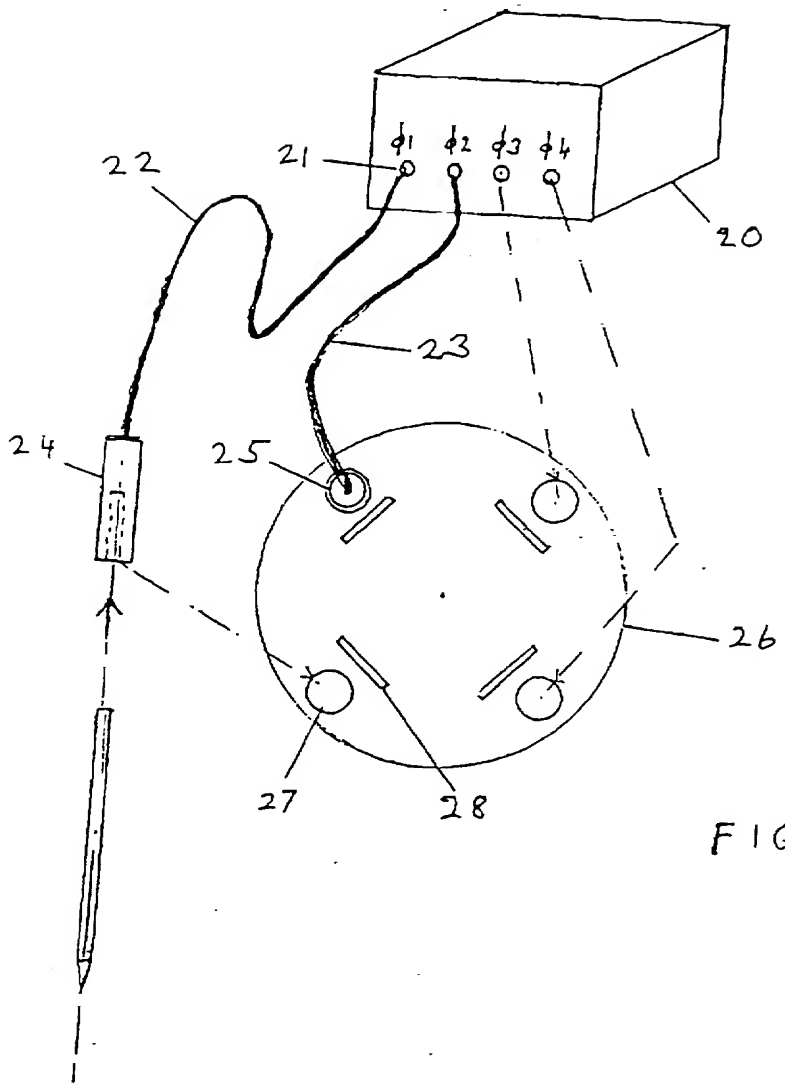

FIG. 3

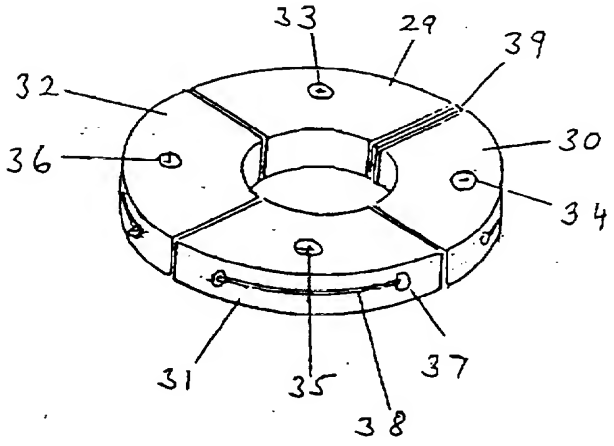

FIG. 4

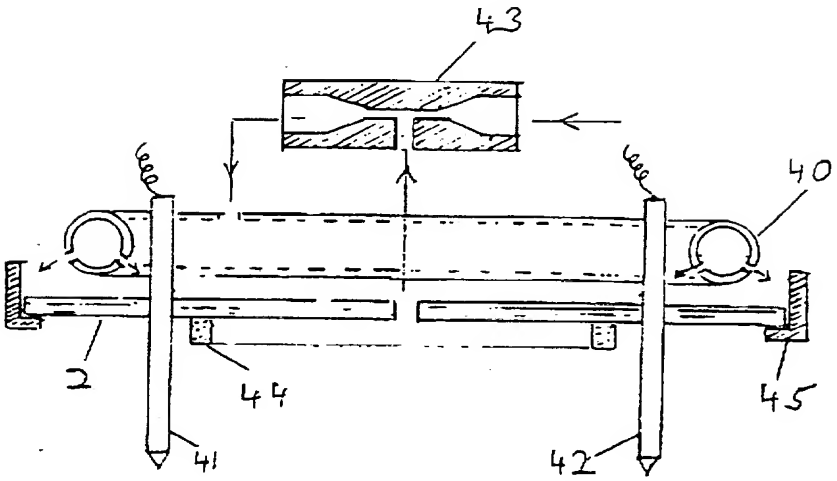

FIG. 5